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HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville, Maryland 20850

m39760

JUL 12 2000

WARNING LETTER

VIA FEDERAL EXPRESS

President and/or Chief Executive Officer
Salton, Inc.
550 Business Center Drive
Mt. Prospect, Illinois 60056

Dear Sir:

We are writing to you because we have obtained information that has revealed a serious regulatory problem involving a product known as "Rejuvenique," which is marketed by your firm. The product consists of a battery-operated electrical facial stimulator that applies electrical current sequentially to various facial muscles, repeatedly contracting them. The product is being sold Over the Counter (OTC) through mail order, and in major department stores such as Sears and The Hecht Company.

An "Owner's Manual" that accompanies Rejuvenique (see enclosed) represents that it tones the skin to reduce the appearance of wrinkling and improves skin tone; that many people notice an overall change in the appearance of their skin with just a few facial sessions; and that the result is a face that is more toned. The Rejuvenique is promoted and sold on the Internet at www.rejuvenique.com. See enclosed website material dated 6/29/00. This material represents, among other things, that the Rejuvenique creates a gradual reduction in the appearance of fine lines and wrinkles resulting in a face that looks more youthful; that the first change people notice is the appearance of reduced puffiness of your face; that it tightens skin and provides increased skin elasticity; that lines that come when one grins will be fewer; and that wrinkles and bags around ones eyes will seem less noticeable. In addition, an "infomercial" represents, among other things, that Rejuvenique tones and tightens loose sagging facial skin; that with its use, 5-10 years are lifted off your face; that frown lines diminish; and that facial lines are shortened.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (Act), the Rejuvenique is considered to be a medical device because it is intended to affect the structure or function of the body. See the above claims for the device. Also, because the Rejuvenique is intended to affect the structure or function of the body by providing electrical current to various facial muscles to repeatedly contract them, it is a device, even if no claims were made for its specific use. The Rejuvenique is similar in technology to a "powered muscle stimulator" device identified under 21 Code of Federal Regulations (CFR) 890.5850.

The law requires that manufacturers of medical devices obtain marketing clearance for their products from the Food and Drug Administration (FDA) before they may offer them for sale. This helps protect the public health by ensuring that new medical devices are shown to be either safe and effective or substantially equivalent to other devices already legally marketed in this country.

Our records do not show that Salton, Inc., obtained marketing clearance before it began offering the Rejuvenique. The kind of information Salton, Inc., needs to submit in order to obtain this clearance is described in the enclosed material entitled "Premarket Notification 510(k) Regulatory Requirements for Medical Devices." In addition, since in terms of technology, the Rejuvenique device is similar to a "powered muscle stimulator," as referenced above, the enclosed "Guidance Document for Powered Muscle Stimulator 510(k)s" may be of assistance when submitting a marketing application to FDA. The FDA will evaluate this information and decide whether this product may be legally marketed.

Because Salton, Inc., does not have marketing clearance from FDA, marketing the Rejuvenique is a violation of the law. In legal terms, the product is adulterated under Section 501(f)(1)(B) and misbranded under Section 502(o) of the Act. The product is adulterated under the Act because Salton, Inc., did not obtain premarket approval based on information developed by the firm that shows the device is safe and effective. The product is misbranded under the Act because Salton, Inc., did not submit information that shows its device is substantially equivalent to other devices that are legally marketed.

The law requires that device labeling bear adequate directions for lay use. However, because Rejuvenique is not safe except under the supervision of a practitioner licensed by state law to direct the use of the device, it is a prescription device for which adequate directions for lay use cannot be prepared or written. The law exempts a prescription device from adequate directions for lay use if it meets all of the conditions of 21 CFR 801.109 (copy enclosed).

The Rejuvenique does not meet all the conditions of 21 CFR 801.109. For example, the product is not sold only to or on the prescription or other order of the above referenced practitioner, for use in the course of his or her professional practice, as required by 21 CFR 801.109(a)(2). Rather, the Rejuvenique is sold through mail order and over the counter in stores, without the requirement for the referenced prescription or other order. Also, the label for the Rejuvenique does not bear the statement "Caution: Federal law restricts this device to sale by or on the order of a _____," the blank to be filled with the word "physician," "dentist," or with the descriptive designation of any other practitioner licensed by law of the State in which he/she practices to use or order the use of the device, as required by 21 CFR 801.109(b)(1).

Because the Rejuvenique is a prescription device and does not meet all the conditions of 21 CFR 801.109, it is in violation of the law. In legal terms, the product is misbranded under Section 502(f)(1) of the Act.

Please note that the law requires that device labeling bear such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe methods or duration of administration or application, in such a manner and form, as are necessary for the protection of the users.

While the referenced Rejuvenique "Owner's Manual" has some of the above referenced warnings, the listing is incomplete. For example, the manual does not provide a warning statement that the device should not be applied transcerebrally; a warning statement that the device should not be used over swollen, infected, or inflamed areas or skin eruptions; or a warning statement that caution should be used in the presence of the following: a. when there is a tendency to hemorrhage following acute trauma or fracture; b. following recent surgical procedures when muscle contraction may disrupt the healing process; and c. over areas of the skin which lack normal sensation.

Because the Rejuvenique Owner's Manual does not have the above and other warnings, the Rejuvenique is in violation of the law. In legal terms, the product is misbranded under Section 502(f)(2) of the Act. The enclosed materials referenced on page 2, the third paragraph, provide a complete listing of contraindications, warnings, precautions, and adverse reactions to be included in the labeling for electrical (powered) muscle stimulators.

The law also requires under Section 510 (j) of the Act that the Rejuvenique be listed. See 21 CFR 807.20(a) (copy enclosed) for who is responsible for listing the Rejuvenique. Our

records do not show that your firm or any other firm has complied with the above requirement. Because the Rejuvenique is not listed, it is in violation of the law. In legal terms, the product is misbranded under Section 502(o) of the Act.

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties (see below). Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

With respect to civil money penalties, the FDA may assess these against you individually and Salton, Inc., for violations of Section 301(a) of the Act; i.e., the introduction or delivery for introduction into interstate commerce of any ... device... that is adulterated or misbranded. Under Section 303(f)(1)(A) of the Act, FDA may impose civil money penalties of up to $15,000 on you as an individual, and a like amount on Salton, Inc., for each violation of a requirement of the Act relating to medical devices, up to a total of $1,000,000 per respondent for all violations. In this case, a violation of referenced Section 301(a) occurs each and every time Salton, Inc., ships a device.

It is necessary for you to take action on these matters now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. Additionally, we ask that you provide the names and addresses of all domestic and foreign manufacturers and distributors from whom you obtain the Rejuvenique devices. If you need more time, let us know why and when you expect to complete your correction and to provide the above requested information. Please direct your response to William F. Defibaugh, Compliance Officer, Orthopedic, Physical Medicine, and Anesthesiology Devices Branch, Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, MD 20850.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issues of premarket clearance for your device, prescription device requirements, and listing requirements, and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-(800) 638-2041 or through the Internet at http://www.fda.gov.

A copy of this letter is being sent to FDA's Chicago District Office. Please send a copy of your response to the District Director, Food and Drug Administration, Chicago District Office (HFR-MW100), 300 S. Riverside Plaza, 5th Floor, Suite 550 South, Chicago, Illinois 60606.

Sincerely yours,

Steve M. Niedelman
ActingDirector
Office of Compliance
Center for Devices and
Radiological Health

Enclosures: As stated

cc w/o Enclosures:

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